Second Medical Use Patents

Enforcement in view of skinny labels and off-label prescriptions

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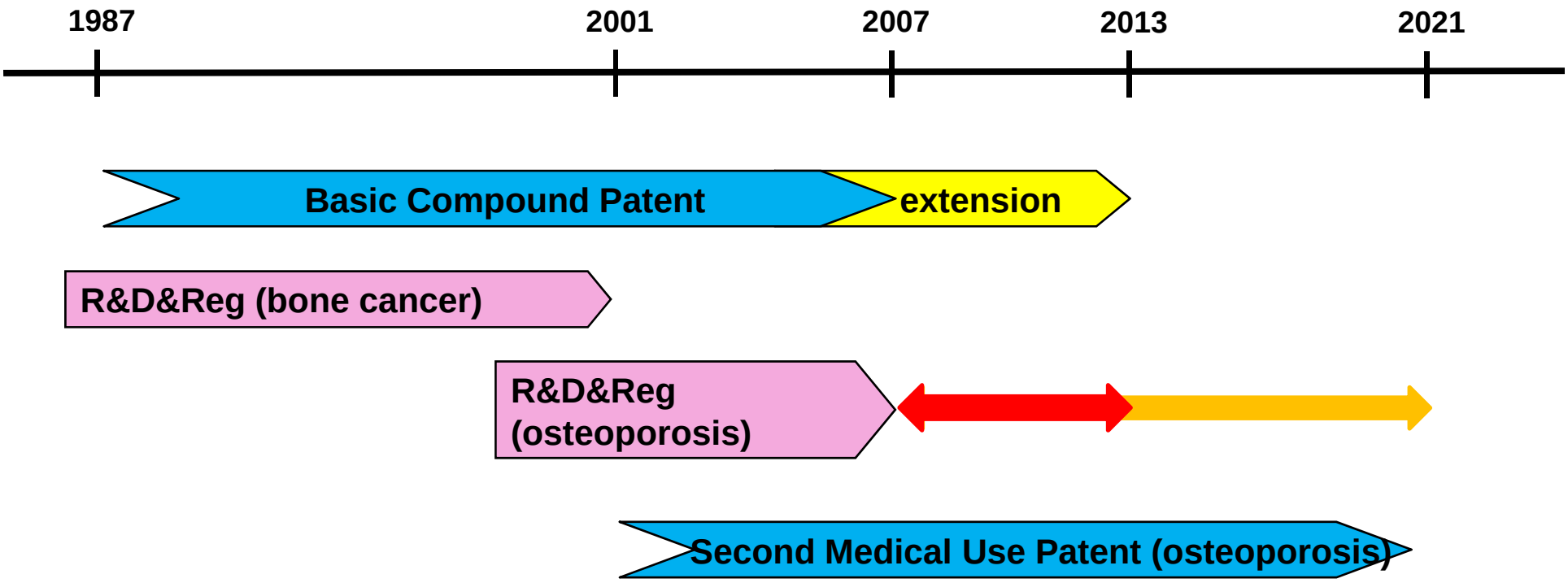
My personal views

Originator‘s perspective

Example: Development of Zoledronic Acid



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Patenting Second Medical Uses

- US: method-of-treatment claims
  - ‘Method of treating disease X by administering compound Y‘
- EPO:
  - Art. 52(4) EPC 1973: therapeutic treatment not patentable
  - G1/83: second medical use patentable in Swiss-type claim format – ‘use of Y for the manufacture of a medicament for the treatment of X’
  - Art. 53(c) EPC 2000: second medical use patentable as use-limited product claims – ‘Compound Y for use in treating disease X‘
- Japan: use-limited product claims
  - E.g. ‘Pharmaceutical composition for treatment of disease X, comprising compound Y’

Neurim v Comptroller (CJEU, C-130/11)

Jacob LJ in referral from UK Court of Appeal:

"29. ... It would be most unfortunate if second medical use patents could not get the benefit of an SPC.

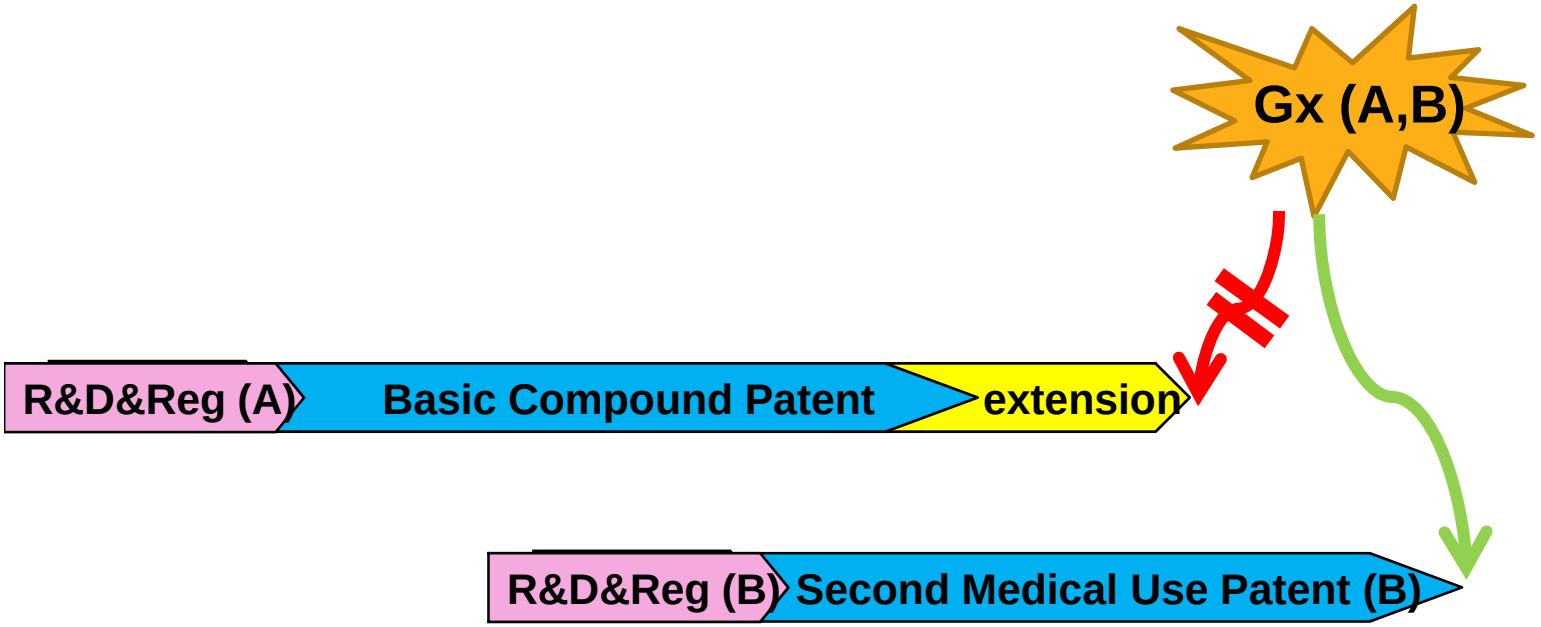
30. In short, if Neurim are wrong, then the Regulation will not have achieved its key objects for large areas of pharmaceutical research: it will not be fit for purpose. ..."

- CJEU-hearing on 15 Mar 2012

Infringement of Second Medical Use Patents

- US:
  - inducement to infringe
  - necessary intent assumed, since patented use on label
- Europe, Japan:
  - direct infringement
- Legal Remedies:
  - Injunction
  - Damages

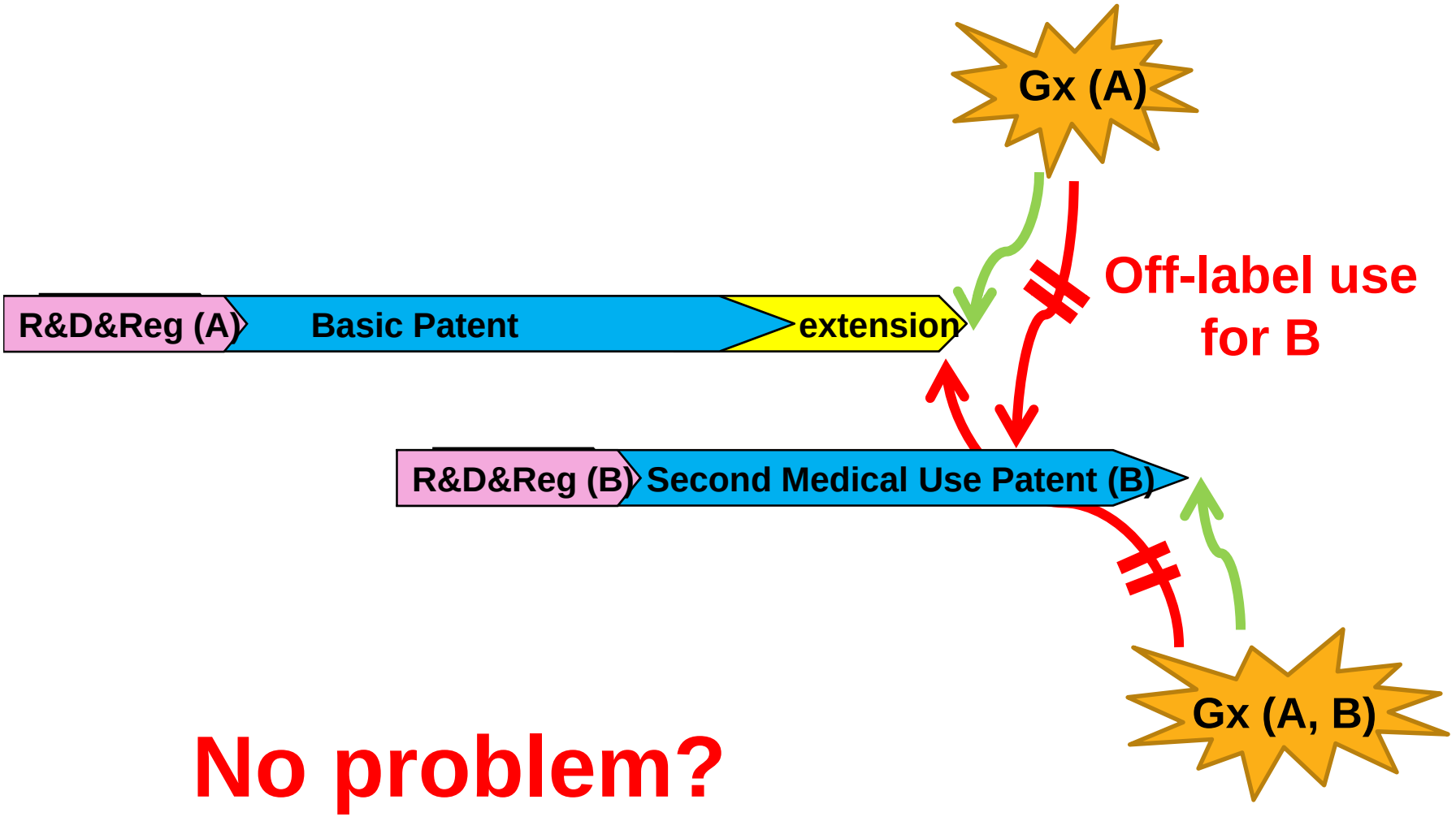
Gx‘ Drug with Indications A and B in Label



‚Carve-out' of Patented Indications by Gx

- US: Section (viii) carve-out already in Hatch-Waxman Act of 1984
  - 21 U.S.C. § 355(j)(2)(A)(viii)
- EU: introduced in 2004
  - Art. 11, 12., Directive 2004/27/EC amending Directive 2001/83/EC (Medicinal Products)
- Japan: possible

Carve-out and Off-label Use



No problem?

Example: Primary Care Drug in Germany

Physician prescribes drug

No indication on prescription

Pharmacist dispenses drug

Incentivized and/or mandatory substitution by cheaper Gx

Payor reimburses drug

Reimbursement irrespective of label

Infringement by Off-label Use

- Highly dependent on facts and evidence
- Little/no case law
- US: Gx‘ knowledge about off-label use insufficient evidence for intent
- Evidence for promotion of off-label use by Gx
- Plausibility of quantities sold by Gx?
- Legal remedies?

Conclusion

- Legislators have demonstrated appreciation of importance of innovation by second medical uses
- Complex interplay of patent law, regulatory law, pricing, reimbursement etc.
- Enforcement vs off-label use difficult
- Legal uncertainty for Gx
- Problem of price reduction after Gx‘ launch
- **Patients‘ problem: insufficient incentive for originators to develop proven drugs for new and important indications?**